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65	Ala Ala Gln Trp Asp Arg Val His Pro Val His Ala Gly Pro Ile Ala	200	205	210
70	Pro Gly Gln Met Arg Glu Pro Arg Gly Ser Asp Ile Ala Gly Thr Thr	215	220	225
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63

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 65 Val Gly Ser Asp Leu Glu Ile Gly Gln His Arg Thr Lys Ile Glu Glu
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69

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74

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75

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78

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81

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82

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<211> Plasmodium falciparum

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Arg Val Leu Asn Gln Leu Asn Tyr Asp Asn Ala Gly Thr Asn Leu Tyr
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65

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84

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85

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Lys Asp Glu Leu Asp Tyr Ala Asn Asp Ile Glu Lys Lys Ile Cys Lys
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87

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55 Val Pro Leu Asp Gln Asp Phe Arg Lys Tyr Thr Ala Phe Thr Ile Pro
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 385 390 395 400

65 Lys Ile Leu Gln Pro Phe Arg Lys Gln Asn Pro Asp Ile Val Ile Tyr
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	Gln	Tyr	Met	Asp	Leu	Tyr	Val	Gly	Ser	Asp	Leu	Glu	Ile	Gly	Gln	
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5	His	Arg	Thr	Lys	Ile	Gln	Glu	Leu	Arg	Gln	His	Leu	Leu	Arg	Trp	Gly
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92

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93

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 1010 1015 1020
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 1100 1105 1110
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 1115 1120 1125
 45
 Ser Asn Glu Val Ser Glu Asn Tyr
 1130 1135
 50
 55

All references referred to in this application, including patent and patent applications, are incorporated herein by reference to the fullest extent possible.

5

Throughout the specification and the claims which follow, unless the context requires otherwise, the word 'comprise', and variations such as 'comprises' and 'comprising', will be understood to imply the inclusion of a stated integer, step, group of integers or group of steps but not to the exclusion of any other integer, step, group of integers or group of steps.

10

The application of which this description and claims forms part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described herein. They may take the form of product, composition, process, or use claims and may include, by way of example and without limitation, the following claims:

15

Claims

1. A method of raising an immune response against a pathogen which comprises administering (i) one or more first immunogenic polypeptides derived from said pathogen; (ii)
5 one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant; wherein the one or more first immunogenic polypeptides, the one or more adenoviral vectors and the adjuvant are administered concomitantly.
2. A method of raising an immune response against a pathogen which comprises
10 administering (i) one or more first immunogenic polypeptides derived from said pathogen co-formulated with an adjuvant; and (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; wherein one or more immunogenic polypeptides and adjuvant, and one or more adenoviral vectors are administered concomitantly.
3. A method of stimulating the production of pathogen-specific CD4+ and/or CD8+ T-cells
15 and/or antibodies in mammals which comprises administering to said mammal (i) one or more first immunogenic polypeptides derived from a pathogen; (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant; wherein the one or
20 more first immunogenic polypeptides, the one or more adenoviral vectors and the adjuvant are administered concomitantly, for example by administering an immunologically effective amount of an aforesaid composition.
4. A method of raising an immune response against a pathogen which consists of (a)
administering (i) one or more first immunogenic polypeptides derived from said pathogen; (ii)
25 one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant, wherein the one or more immunogenic polypeptide, the one or more adenoviral vector and the adjuvant are administered concomitantly; and (b) optionally repeating the steps of (a).
5. A method of raising an immune response against a pathogen which comprises
30 administering (i) one or more first immunogenic polypeptides derived from said pathogen; (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant; wherein the one or more first immunogenic polypeptides, the one or more adenoviral vectors and the adjuvant are administered concomitantly; and wherein the method does not
35 involve administering any priming dose of immunogenic polypeptide or polynucleotide encoding immunogenic polypeptide.

6. A method according to any one of claims 1 to 5 wherein one or more immunogenic polypeptides, one or more adenoviral vectors and an adjuvant are co-formulated.
7. A method according to any one of claims 1 to 5 wherein production of pathogen specific CD4+ T-cells and CD8+ T-cells and antibodies is stimulated.
- 5 8. A vaccine composition comprising (i) one or more first immunogenic polypeptides derived from a pathogen; (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotide encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant.
9. A method or vaccine composition according to any one of claims 1 to 8 wherein one or
10 more of said one or more first immunogenic polypeptides is substantially the same as one or more of said one or more second immunogenic polypeptides.
10. A method or vaccine composition according to any one of claims 1 to 8 wherein one or more of said one or more first immunogenic polypeptides contains at least one antigen which is substantially the same as an antigen contained in one or more of said one or more second
15 immunogenic polypeptides.
11. A method or vaccine composition according to any one of claims 1 to 10 wherein one or more the first immunogenic polypeptides comprises at least one T cell epitope.
12. A method or vaccine composition according to any one of claims 1 to 11 wherein the one or more first immunogenic polypeptide comprises at least one B cell epitope.
- 20 13. A method or vaccine composition according to any one of claims 1 to 12 wherein one or more of said one or more first immunogenic polypeptides and one or more of said one or more second immunogenic polypeptides share one or more identical B-cell and/or T-cell epitopes.
14. A method or vaccine composition according to any one of claims 1 to 8 wherein none of the one or more of said one or more first immunogenic polypeptides is substantially the same as
25 or contains any antigen in common with one or more of said one or more second immunogenic polypeptides.
15. A method or vaccine composition according to any one of claims 1 to 14 wherein one or more of the adenoviral vectors is derived from a human adenovirus.
16. A method or vaccine composition according to claim 15 wherein the human adenovirus serotype is selected from Ad1, Ad2, Ad4, Ad5, Ad6, Ad11, Ad 24, Ad34 and Ad35.
30
17. A method or vaccine composition according to any one of claims 1 to 14 wherein one or more of the adenoviral vectors is derived from a non-human primate adenovirus.
18. A method or vaccine composition according to claim 17 wherein the non-human primate adenovirus serotype is selected from chimpanzee adenovirus serotypes Pan5, Pan6, Pan7 and
35 Pan9.
19. A method or vaccine composition according to any one of claims 1 to 18 wherein the pathogen is HIV.

20. A method or vaccine composition according to claim 19 wherein the immunogenic polypeptides contain HIV derived antigens which are selected from Env, Nef, Gag, and Pol and immunogenic derivatives thereof and immunogenic fragments thereof.
21. A method or vaccine composition according to claim 20 wherein a first immunogenic polypeptide is p24-RT-Nef-p17.
22. A method or vaccine composition according to claim 20 or claim 21 wherein a second immunogenic polypeptide is Gag-RT-Nef.
23. A method or vaccine composition according to any one of claims 1 to 18 wherein the pathogen is *Plasmodium falciparum* and/or *Plasmodium vivax*.
24. A method or vaccine composition according to claim 23 wherein the immunogenic polypeptides contain antigens derived from *Plasmodium falciparum* and/or *Plasmodium vivax* which are selected from circumsporozoite (CS) protein, MSP-1, MSP-3, AMA-1, LSA-1, LSA-3 and immunogenic derivatives thereof or immunogenic fragments thereof.
25. A method or vaccine composition according to claim 24 wherein a/the immunogenic polypeptide is the hybrid protein RTS.
26. A method or vaccine composition according to claim 25 wherein RTS is presented in the form of a mixed particle known as RTS,S.
27. A method or vaccine composition according to any one of claims 24 to 26 wherein a/the immunogenic polypeptide encoded by a polynucleotide is the CS protein from *Plasmodium falciparum* or immunogenic fragment thereof.
28. A method or vaccine composition according to any one of claims 1 to 18 wherein the pathogen is *Mycobacterium tuberculosis*.
29. A method or vaccine composition according to any one of claims 1 to 28 wherein the adjuvant comprises a preferential stimulator of Th1 responses.
30. A method or vaccine composition according to claim 29 wherein the adjuvant comprises QS21 and/or 3D-MPL and/or CpG.
31. A method or vaccine composition according to claim 30 wherein the adjuvant comprises QS21 and 3D-MPL.
32. A method or vaccine composition according to any one of claims 1 to 31 wherein the adjuvant contains an oil-in-water emulsion.
33. A method or vaccine composition according to any one of claims 1 to 31 wherein the adjuvant contains liposomes.
34. A method of stimulating an immune response in a mammal which comprises administering to a subject an immunologically effective amount of a vaccine composition according to any one of claims 8 to 33.
35. Use of a vaccine composition according to any one of claim 8 to 33 in the manufacture of a medicament for stimulating an immune response in a mammal.

36. A vaccine composition according to any one of claims 8 to 33 for use in stimulating an immune response in a mammal.

37. A kit comprising (i) one or more first immunogenic polypeptides derived from a pathogen; (ii) one or more adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more second immunogenic polypeptides derived from said pathogen; and (iii) an adjuvant.

38. A kit comprising (i) one or more first immunogenic polypeptides derived from a pathogen and an adjuvant; and (ii) one or more second adenoviral vectors comprising one or more heterologous polynucleotides encoding one or more immunogenic polypeptides derived from said pathogen.

39. A method, or vaccine, or kit, or use according to any preceding claim wherein the first immunogenic polypeptide comprises p24-RT-Nef-p17, the adjuvant comprises 3D-MPL and QS21 in a liposome such as adjuvant B herein, and the adenoviral vector comprises a chimpanzee adenovirus serotype Pan7 vector comprising a polynucleotide encoding the immunogenic polypeptide Gag-RT-Nef, optionally codon optimised.

40. A method, or vaccine, or kit, or use according to any preceding claim wherein one, or two, or all of the polypeptide, adenoviral vector and adjuvant components are combined with a pharmaceutically acceptable excipient.

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Figure 1

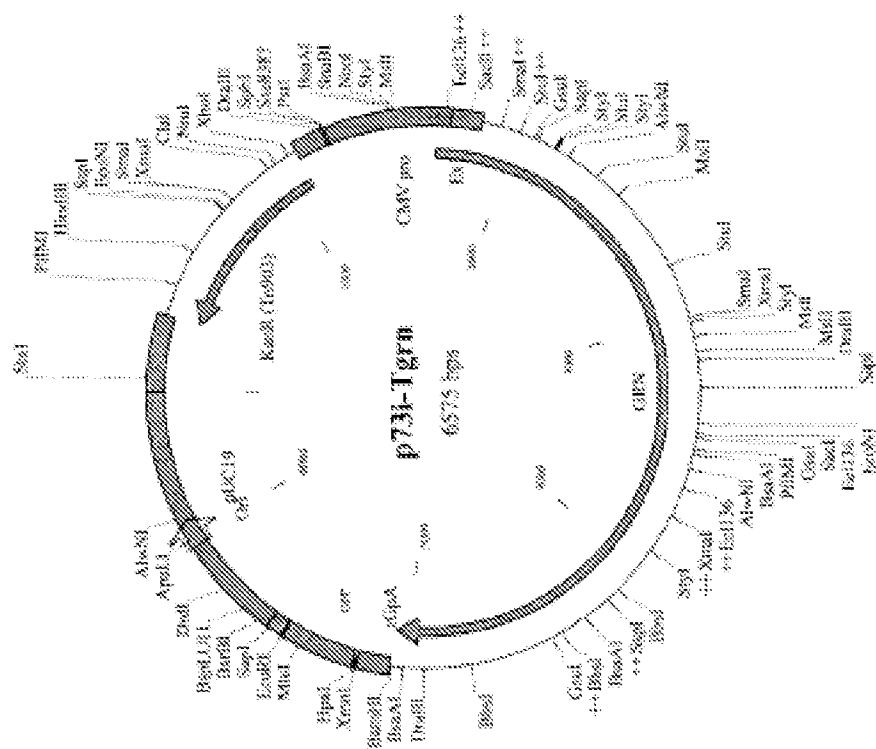
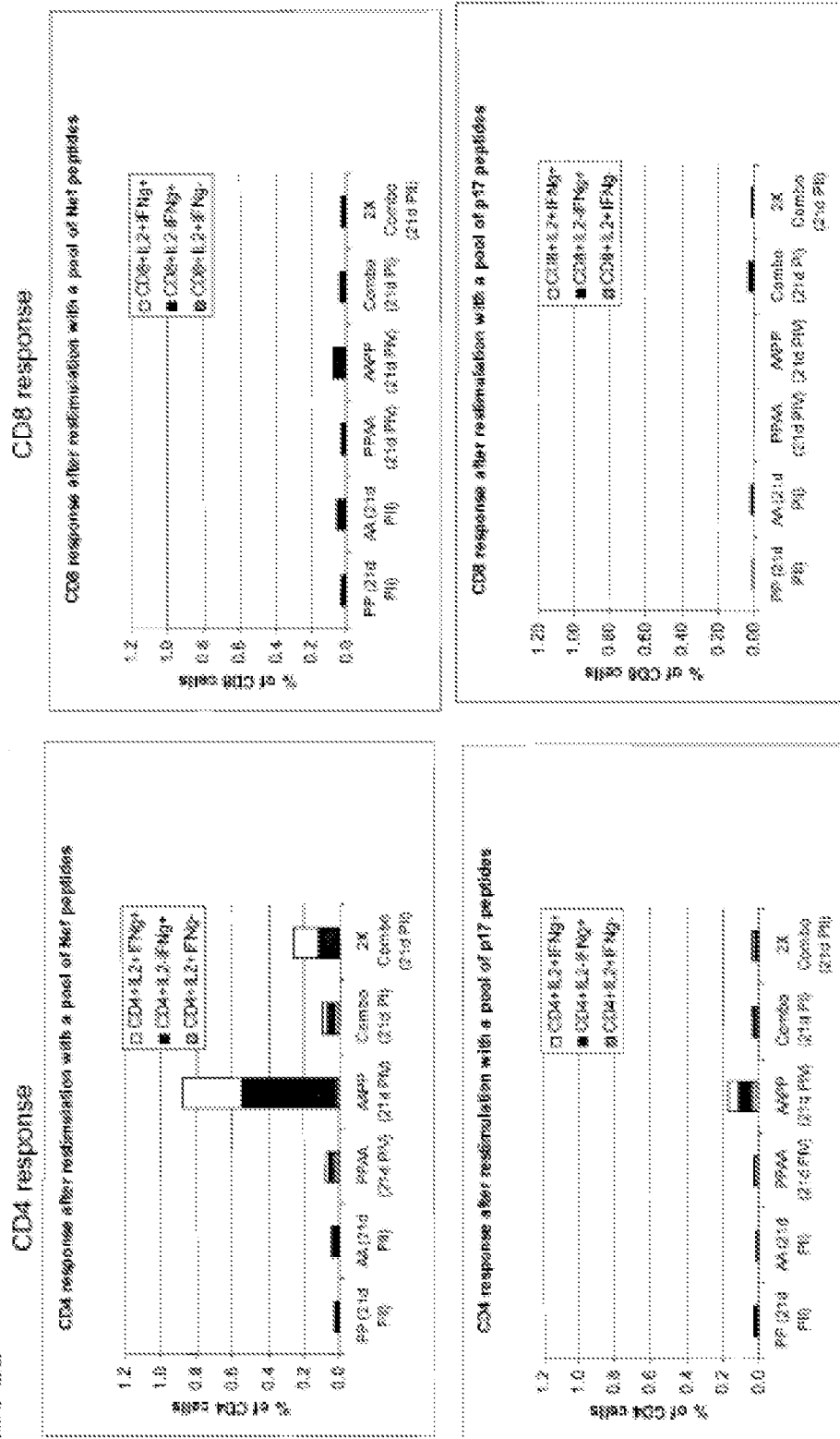
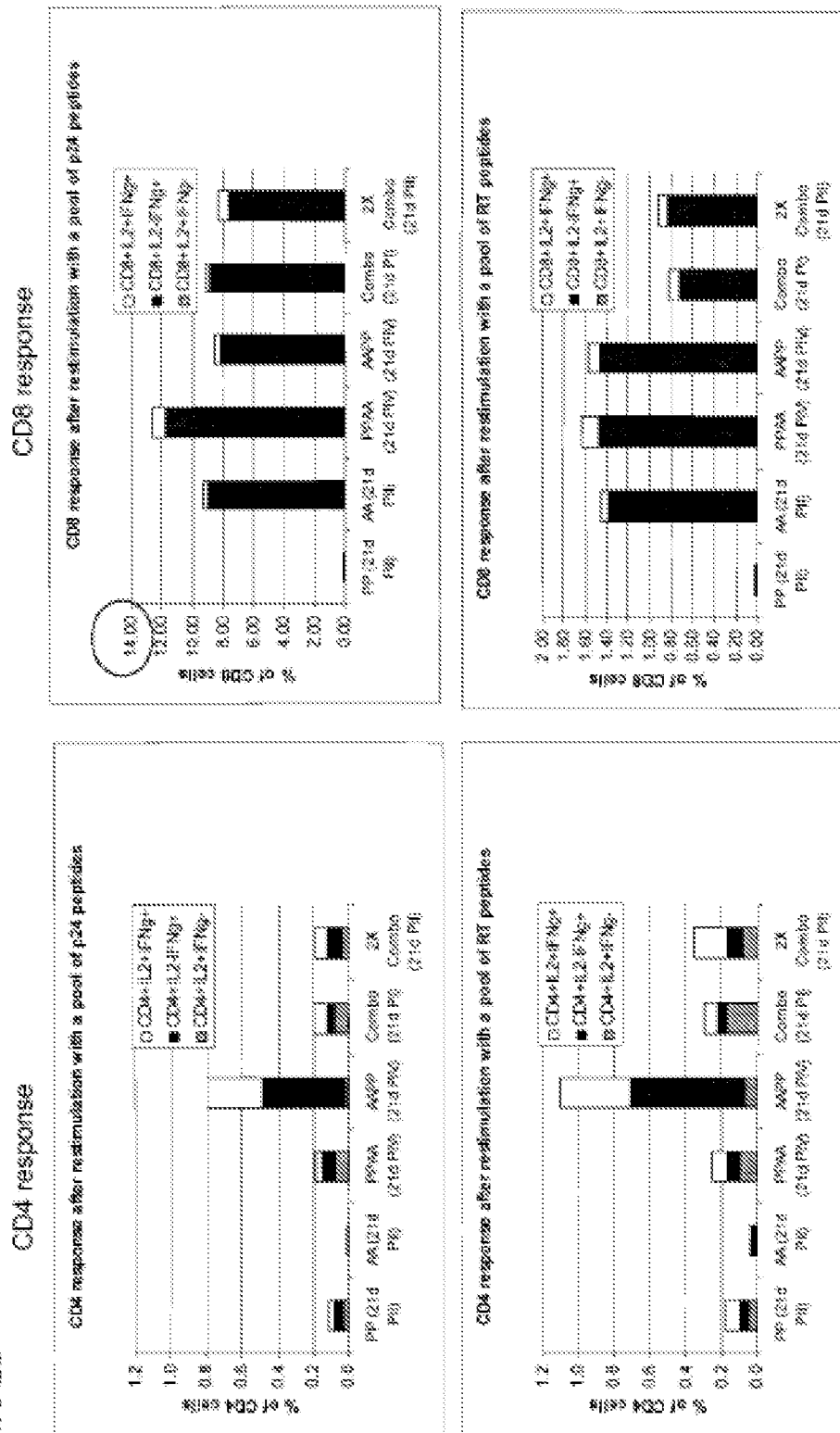


Figure 2a



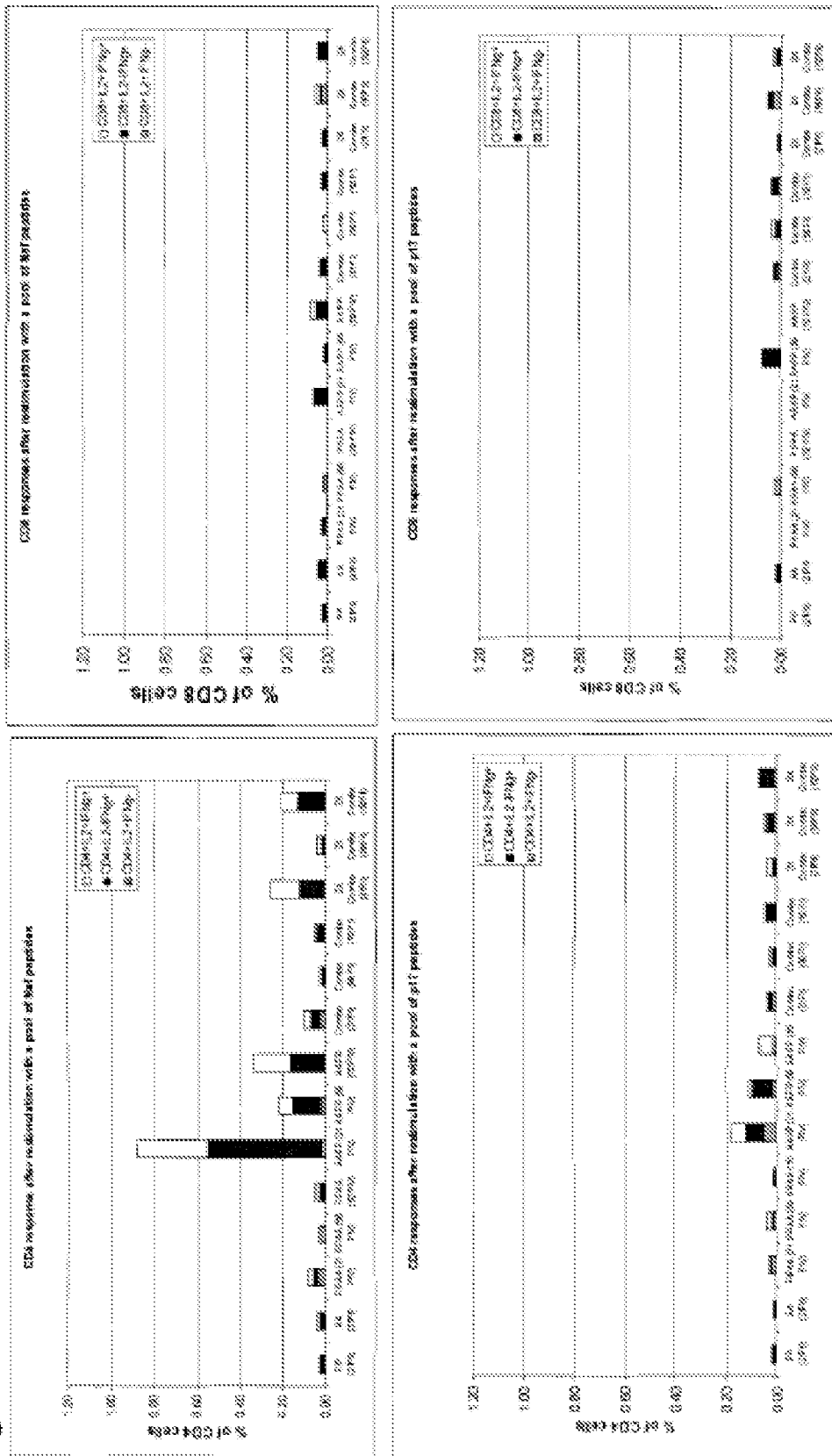
3/27

Figure 2b



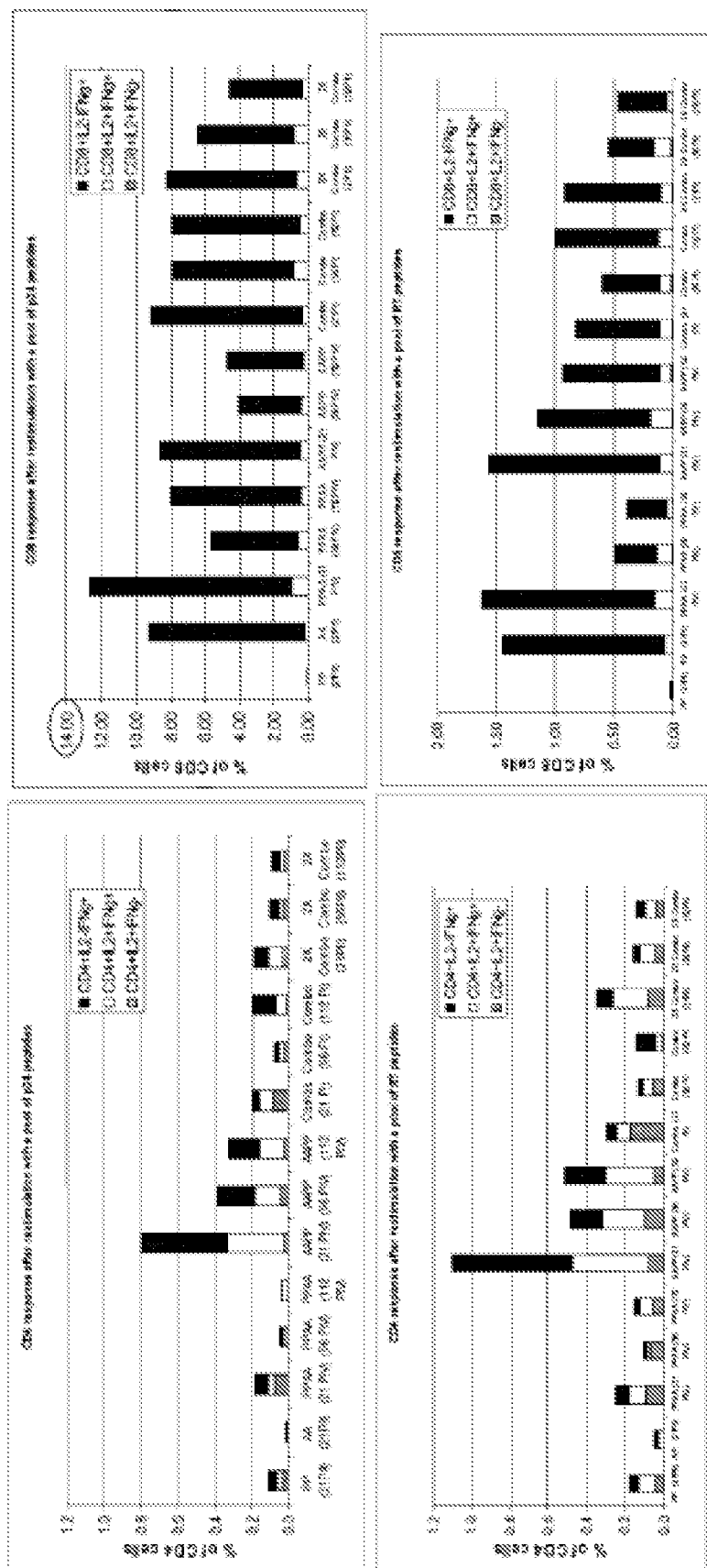
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Figure 3a



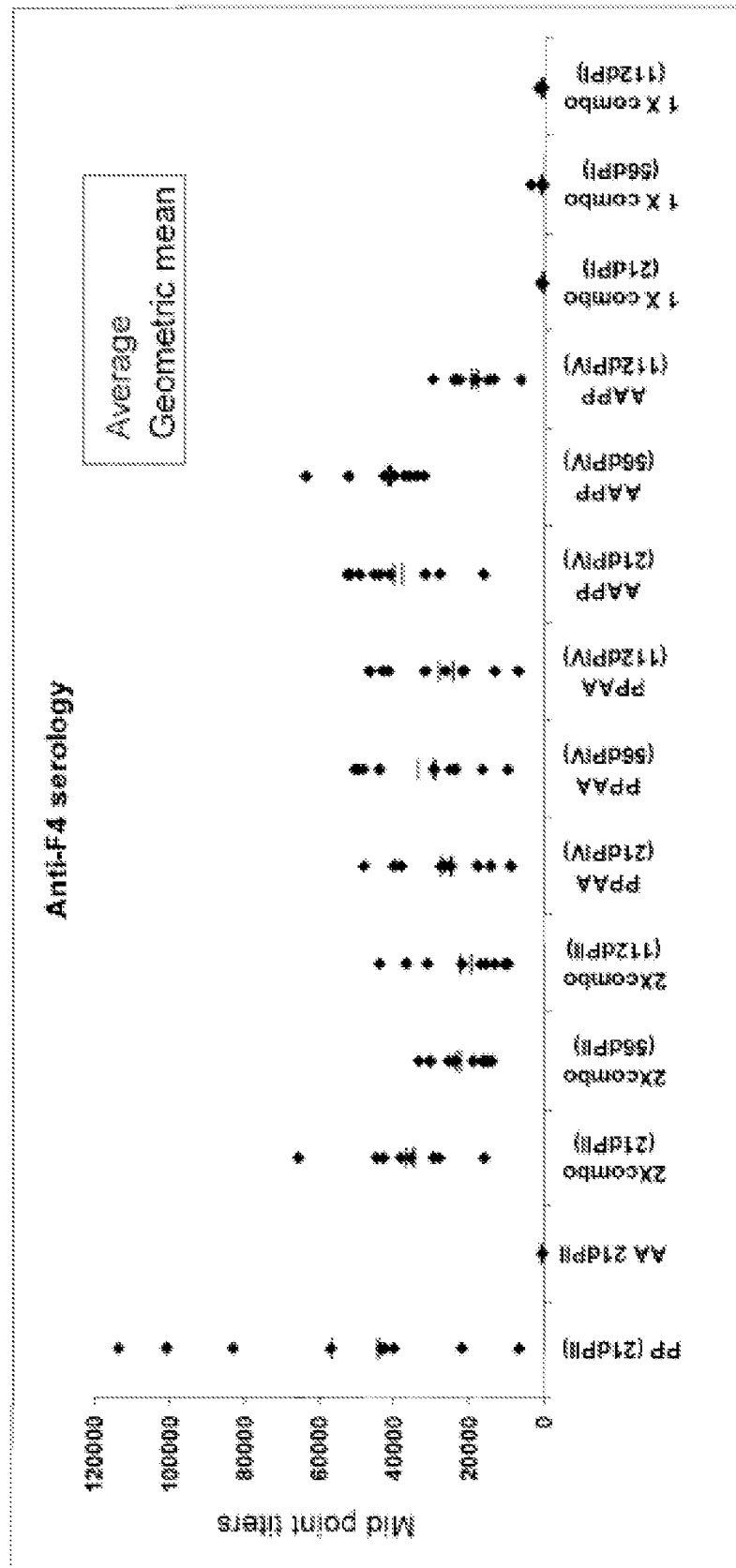
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Figure 3b



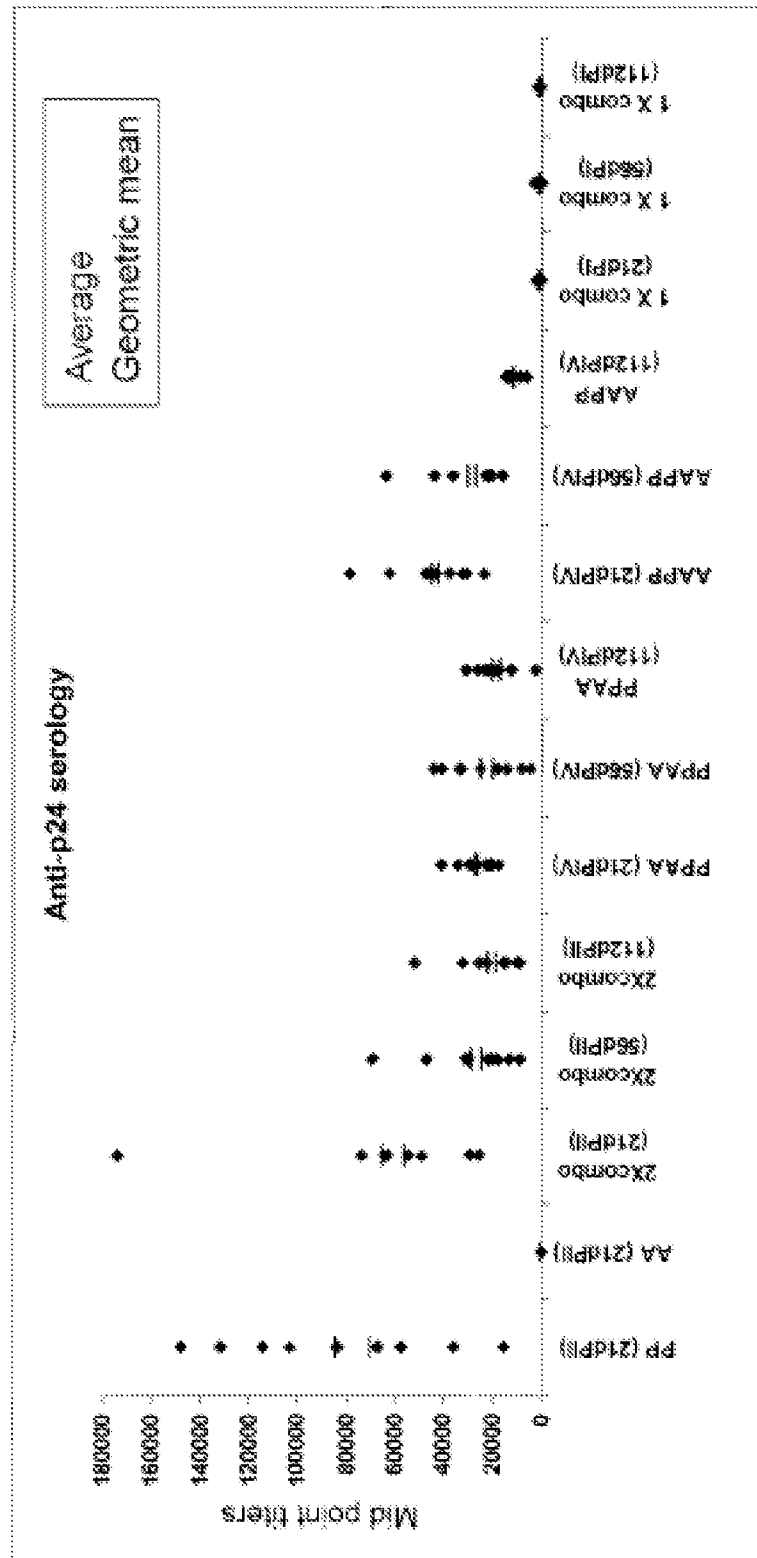
6/27

Figure 4



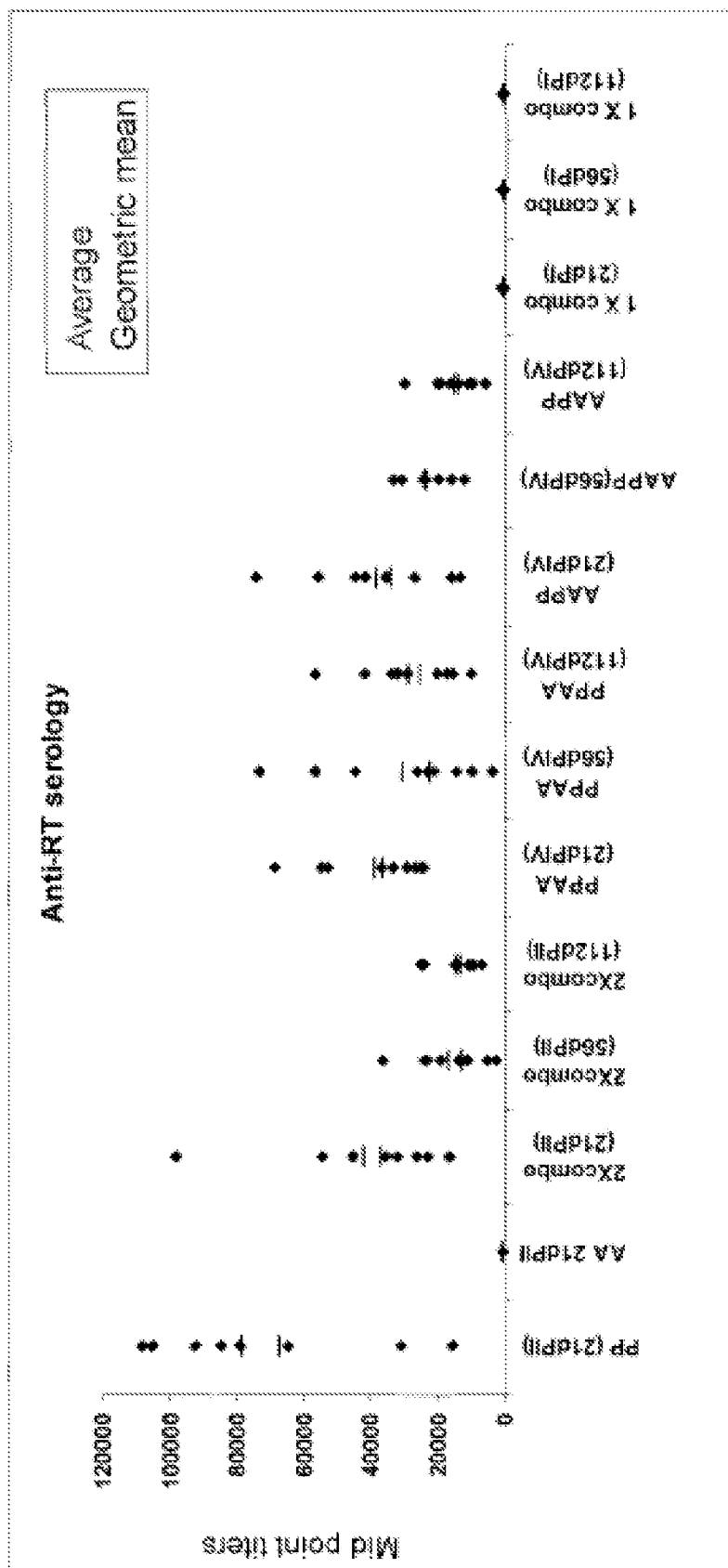
7/27

Figure 5



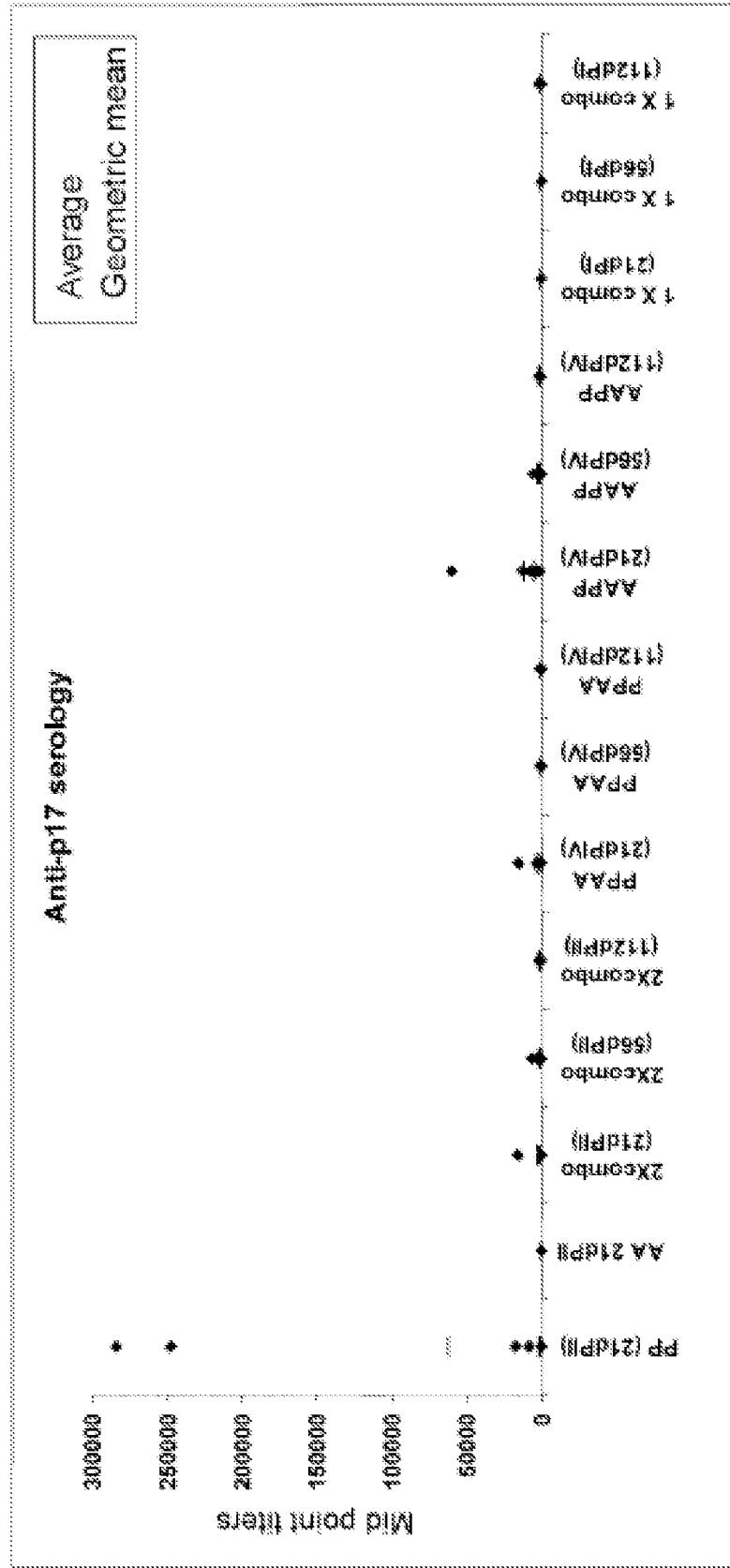
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Figure 6



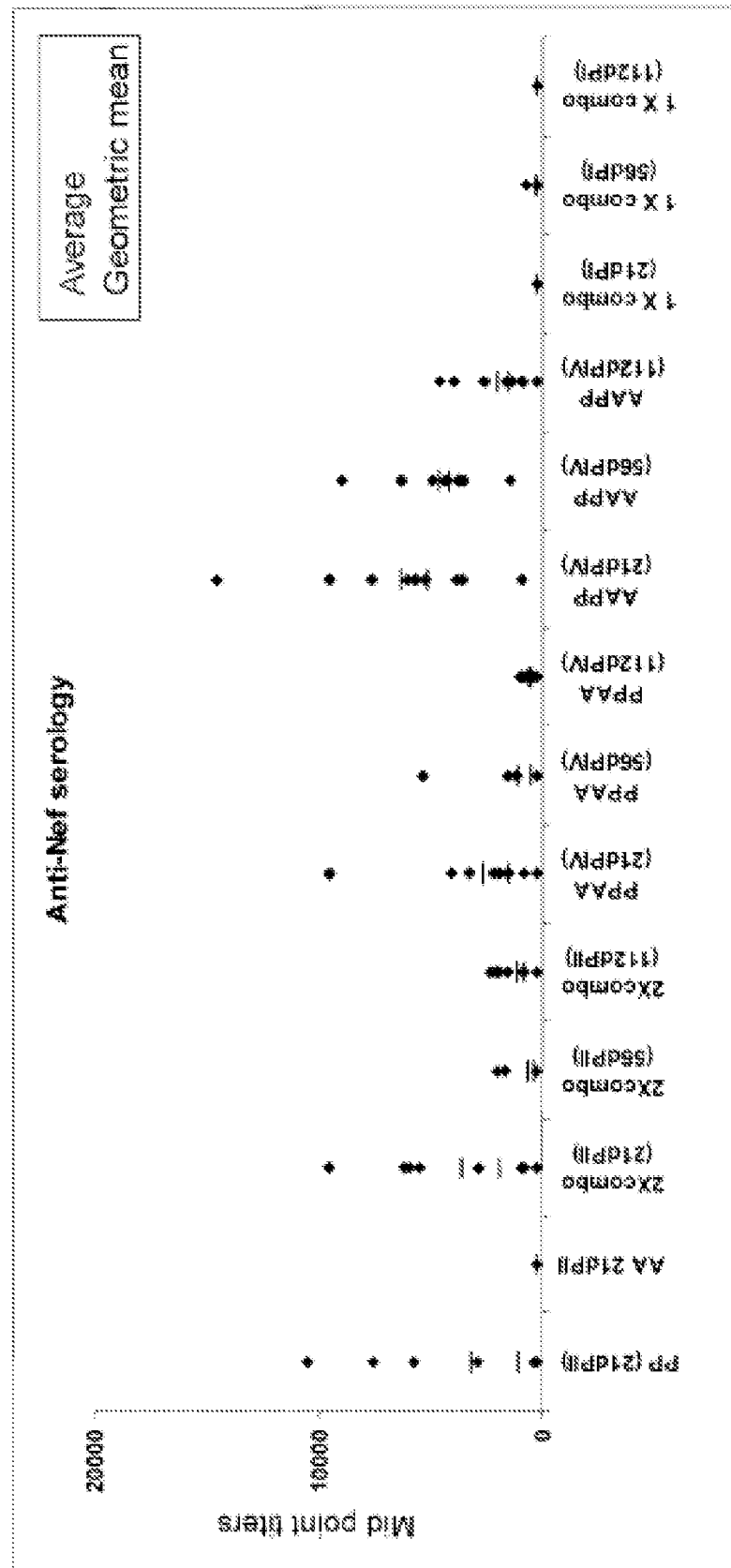
9/27

Figure 7



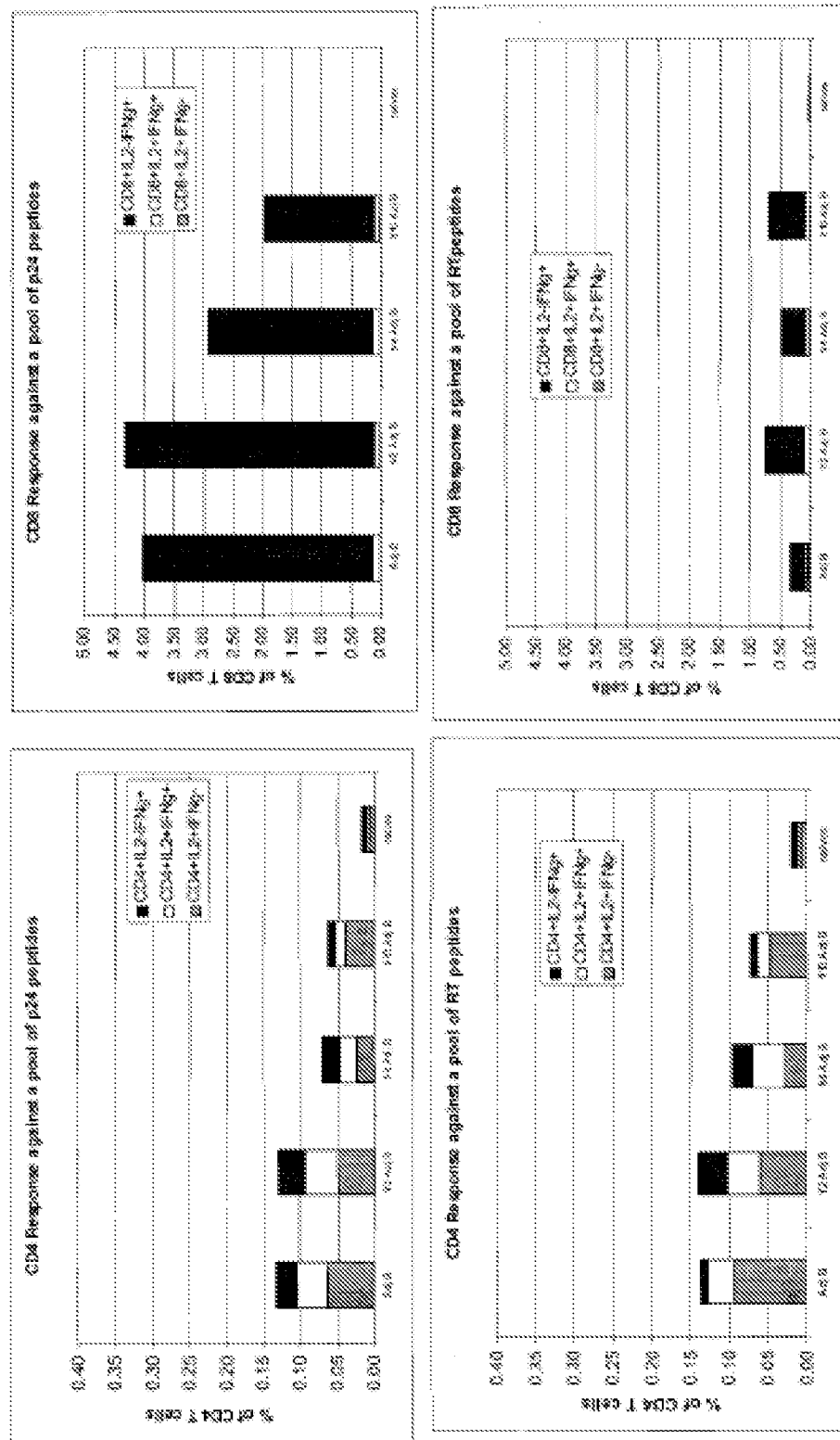
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Figure 8



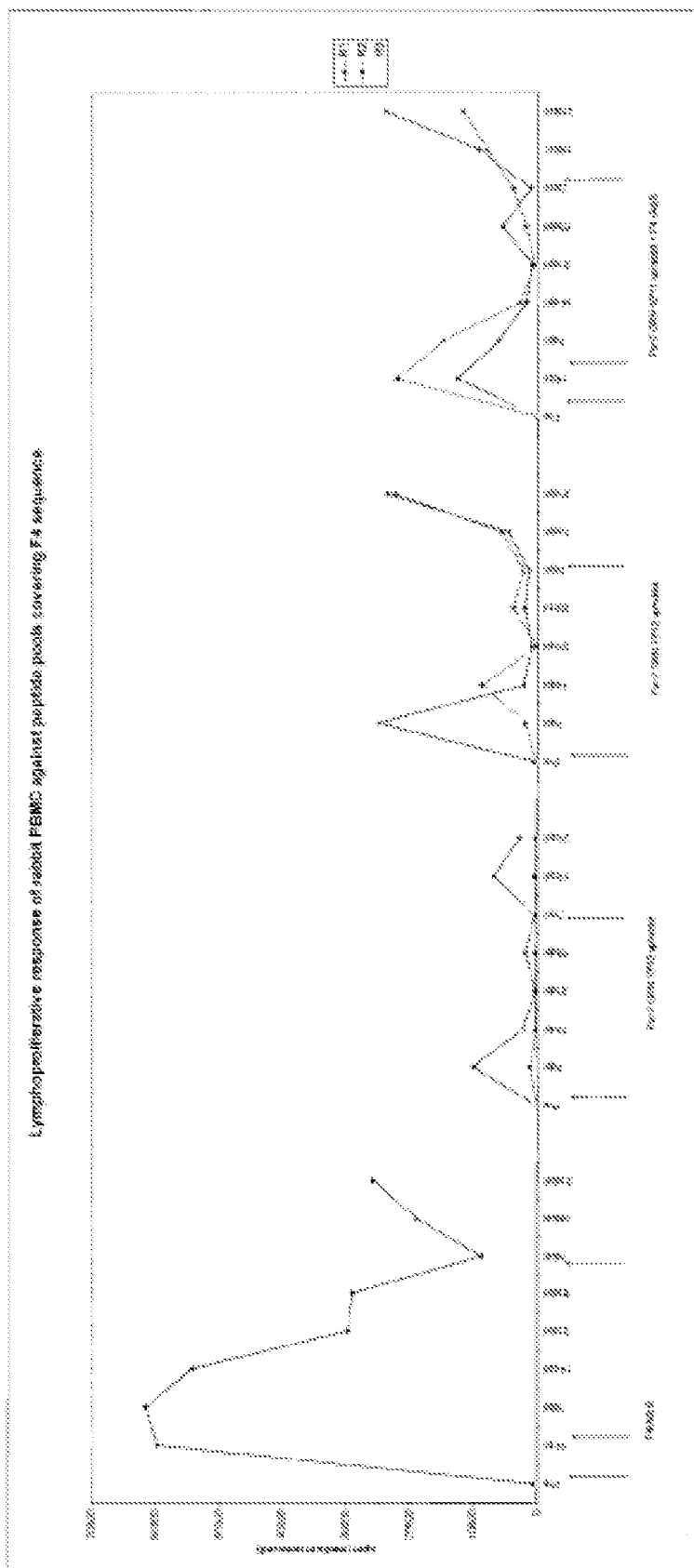
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Figure 9



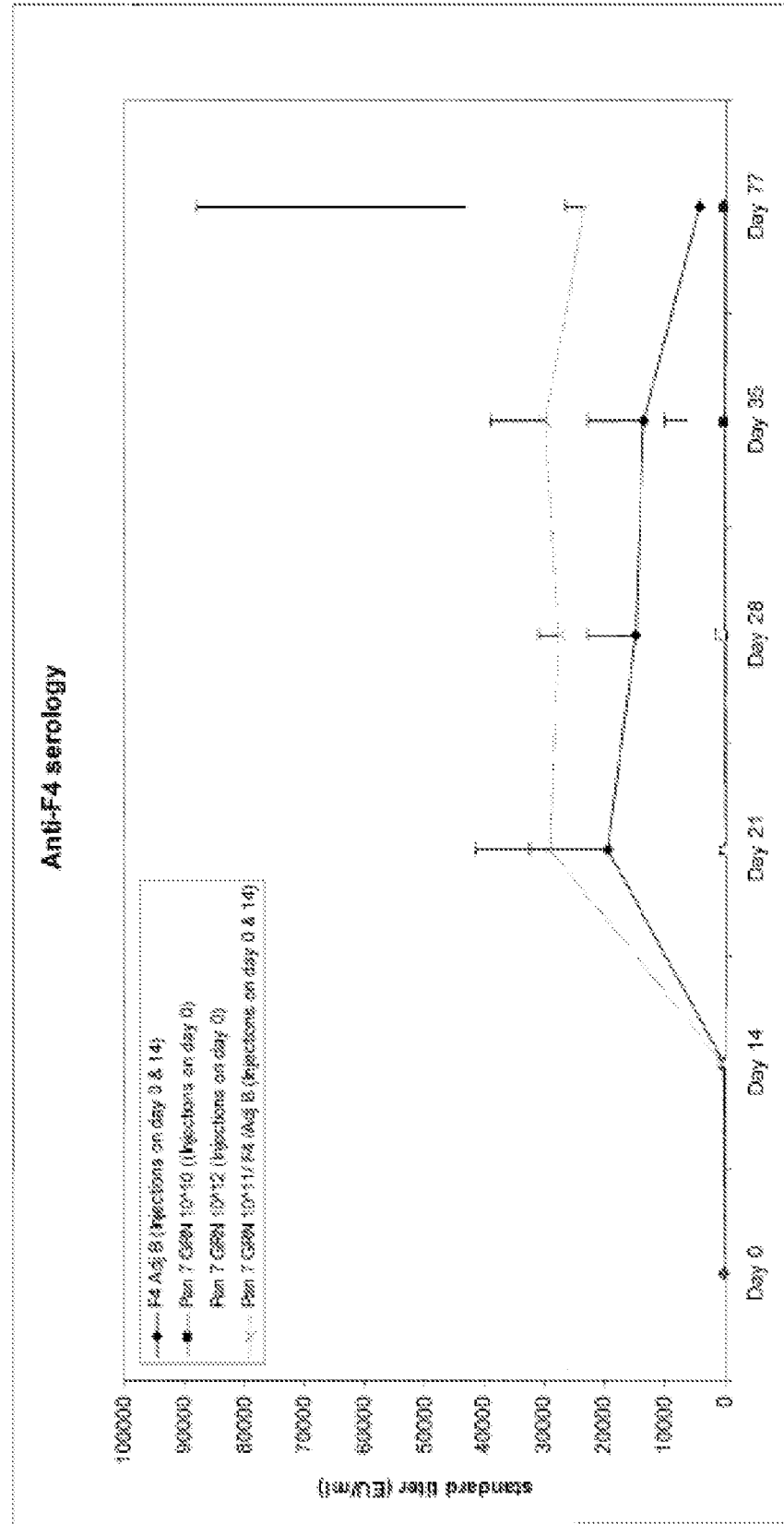
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Figure 10



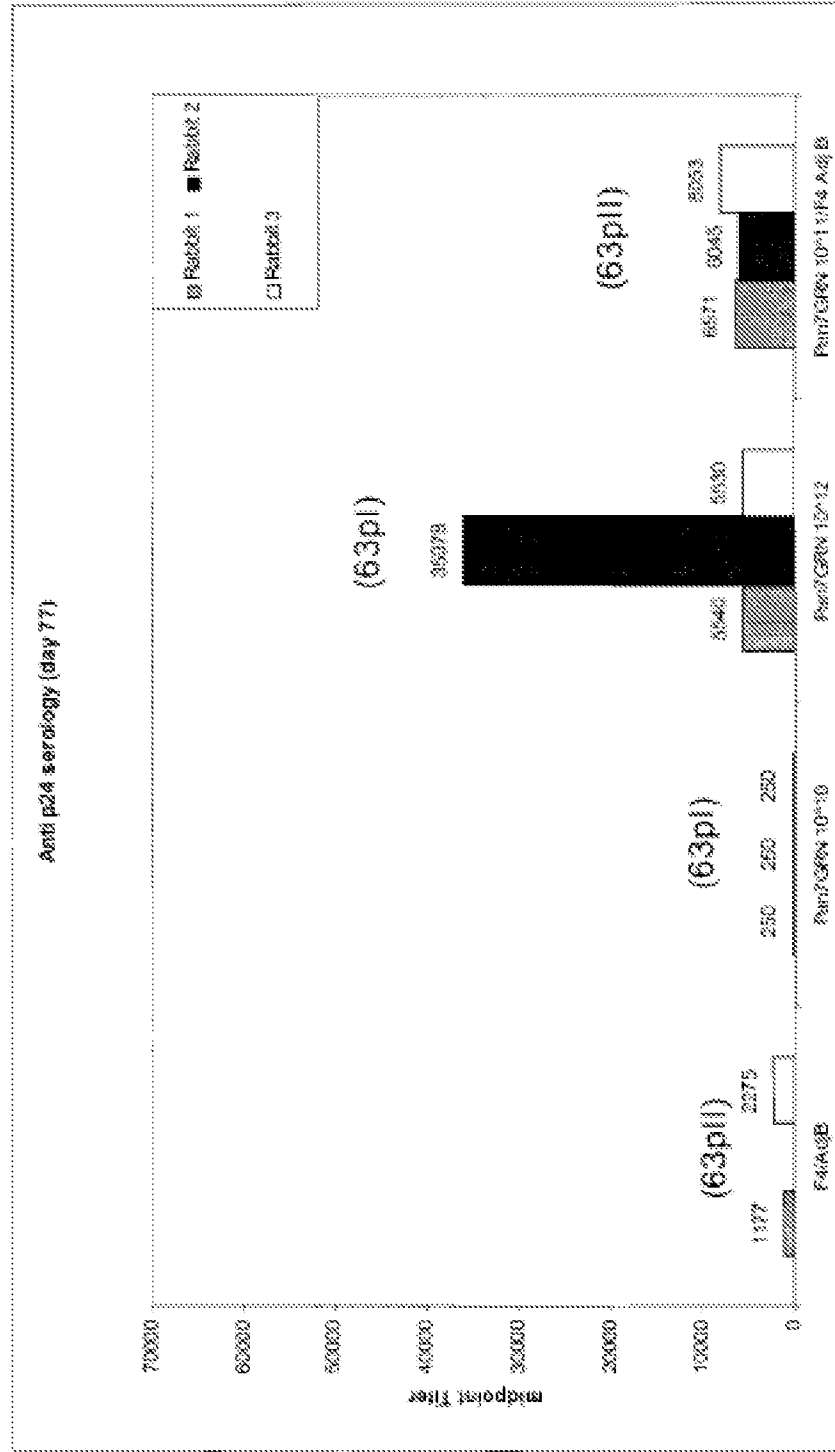
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Figure 11



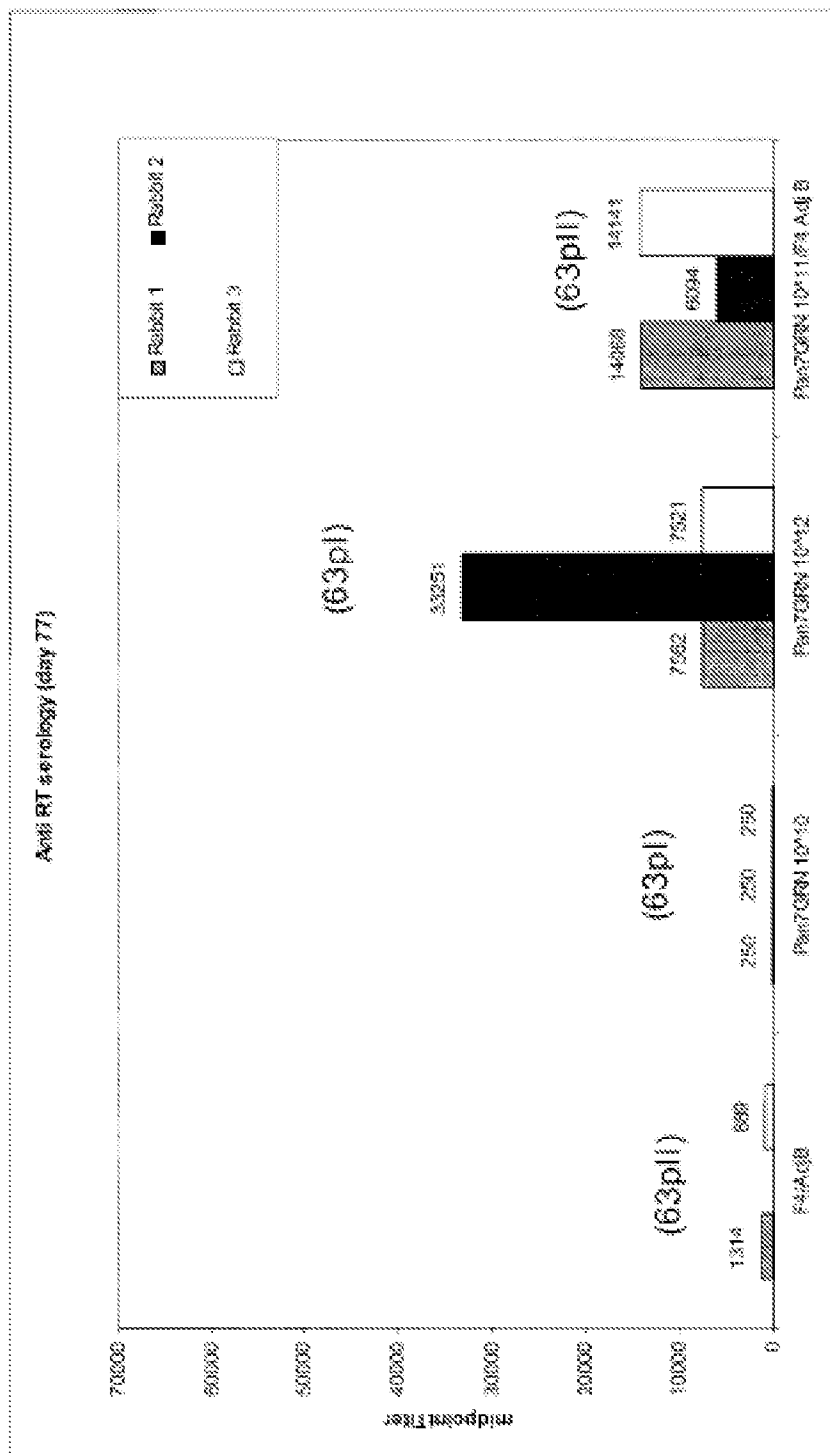
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Figure 12a



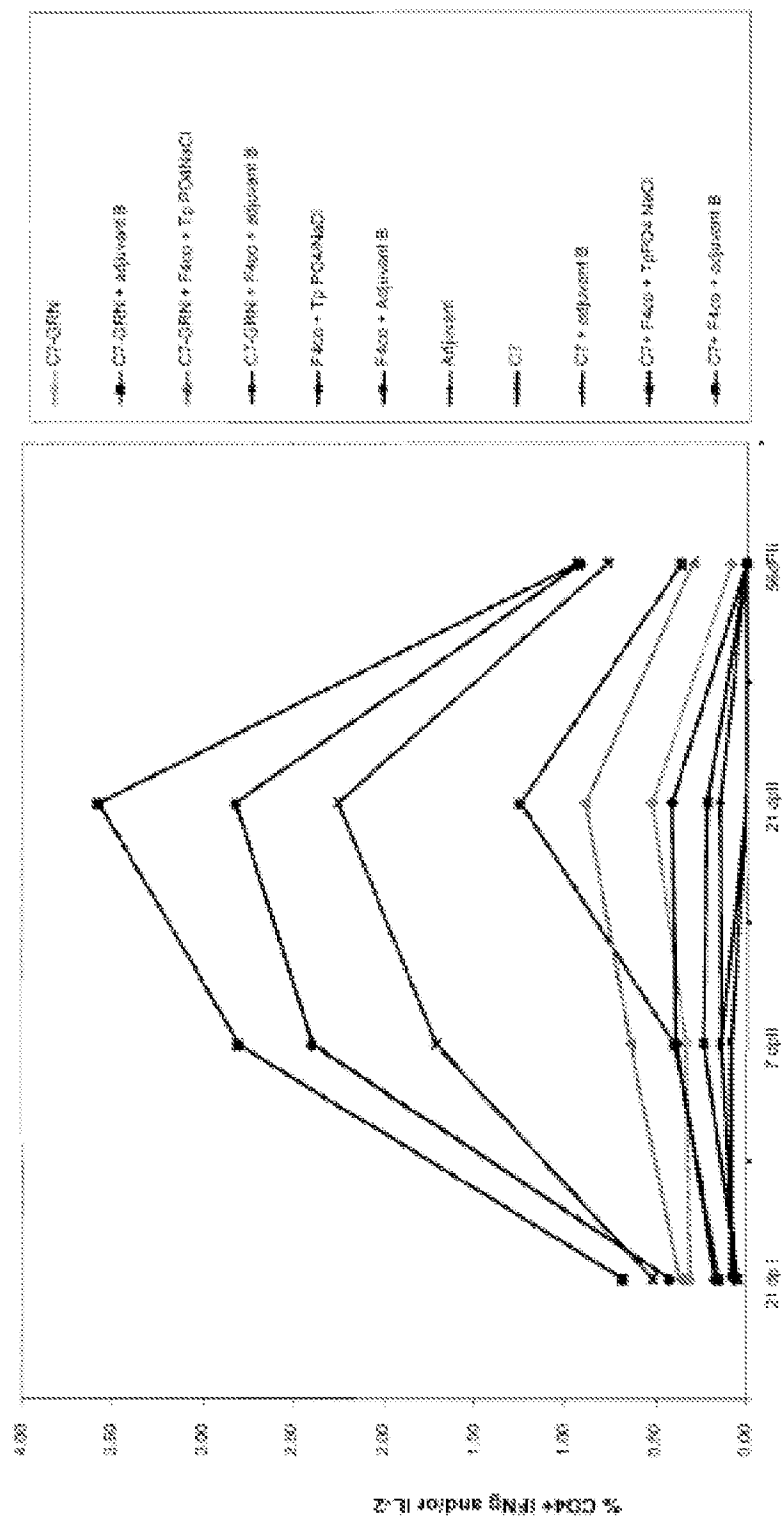
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Figure 12b



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Figure 13



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Figure 15A

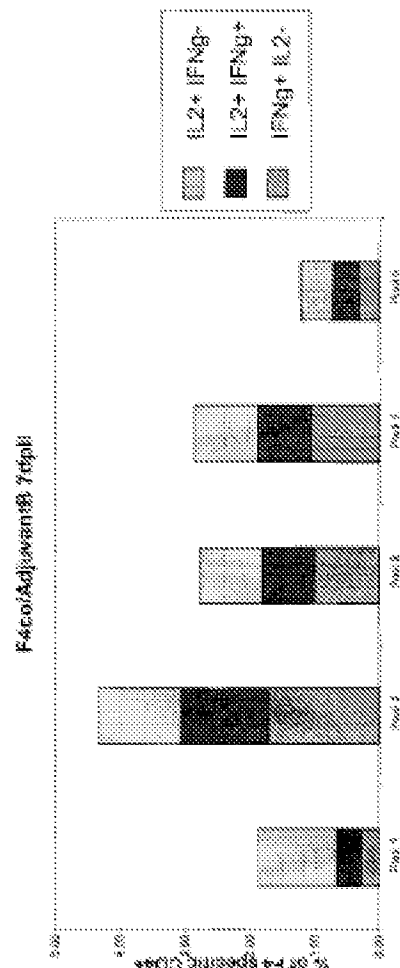
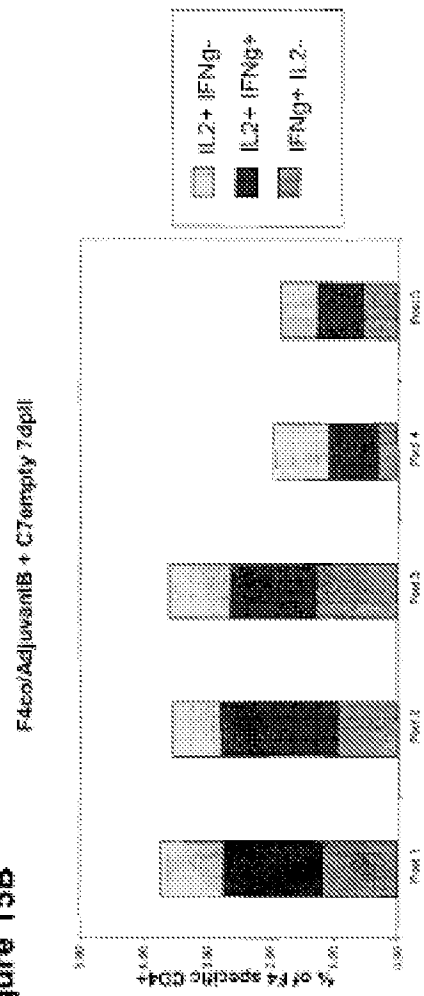
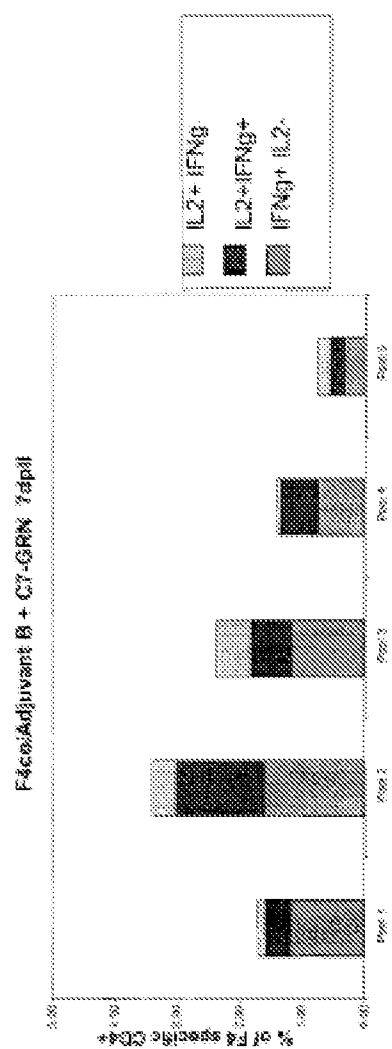


Figure 15B



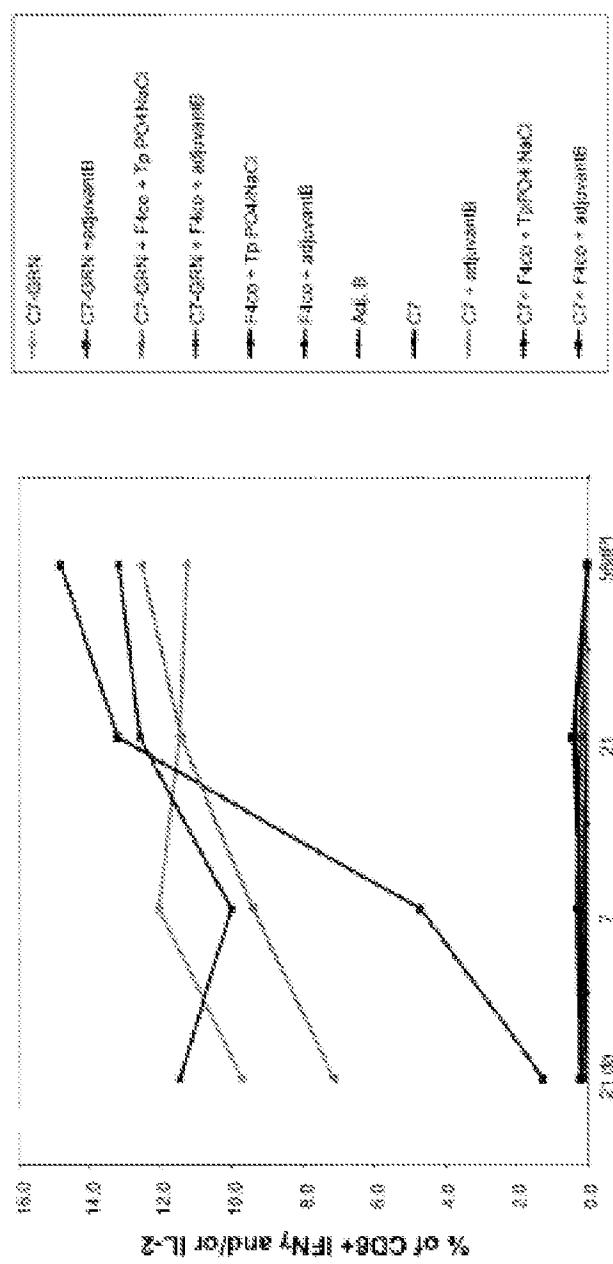
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Figure 15C



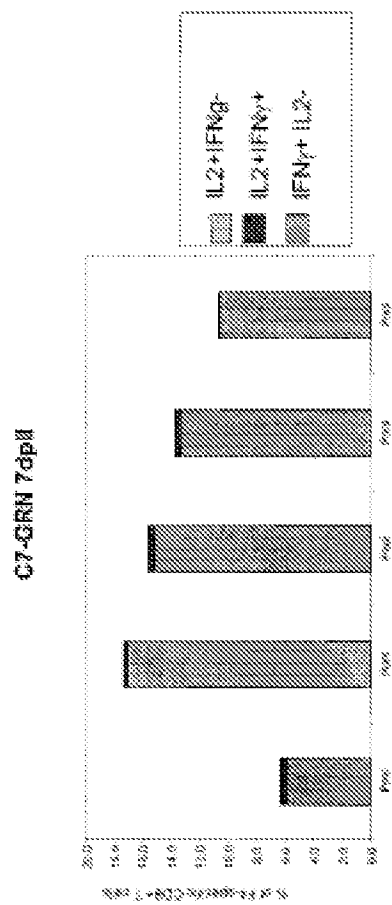
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Figure 16



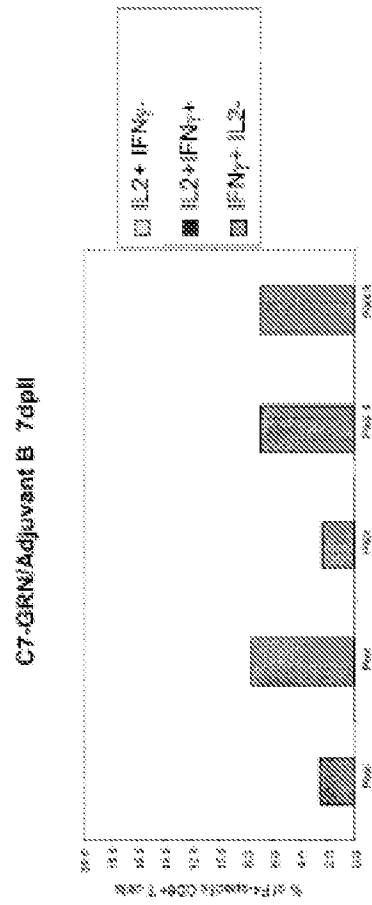
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Figure 17A



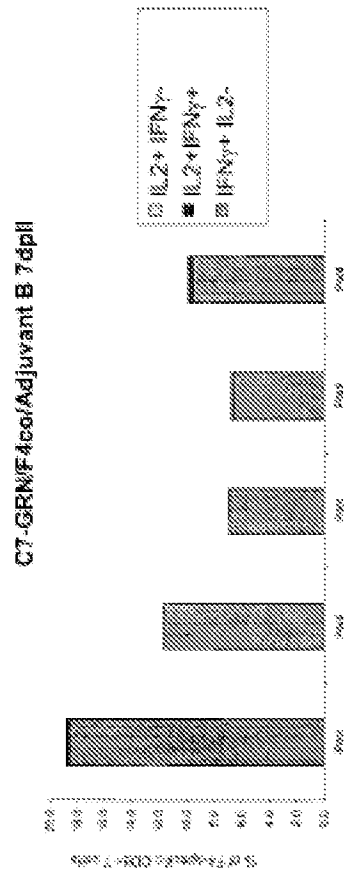
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Figure 17B



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Figure 17 C



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Figure 18

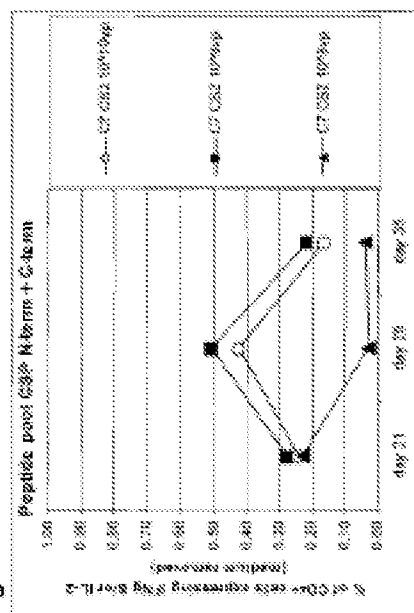
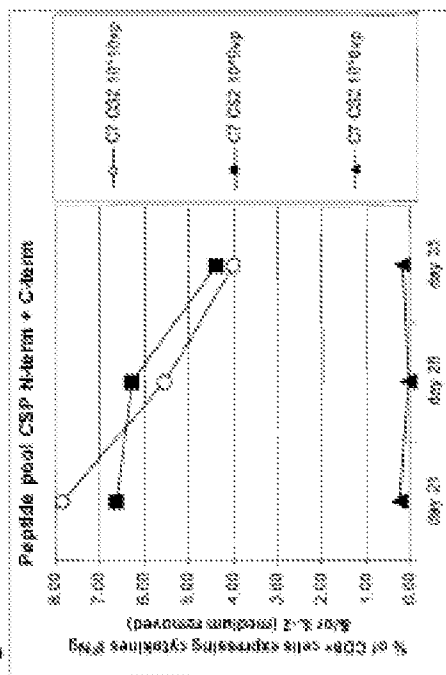


Figure 19



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Figure 20

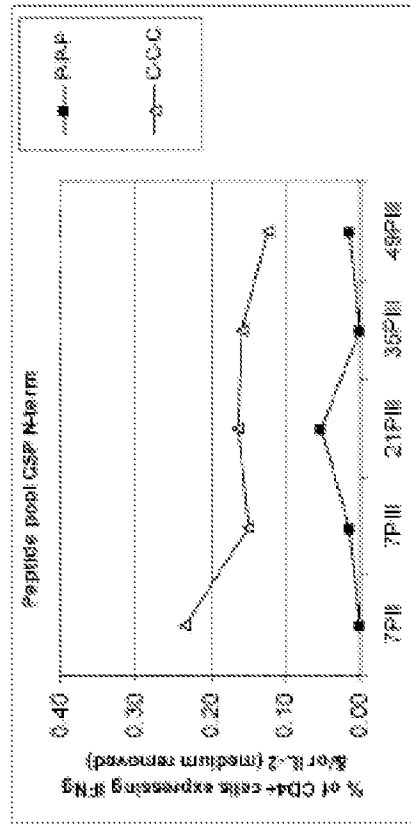
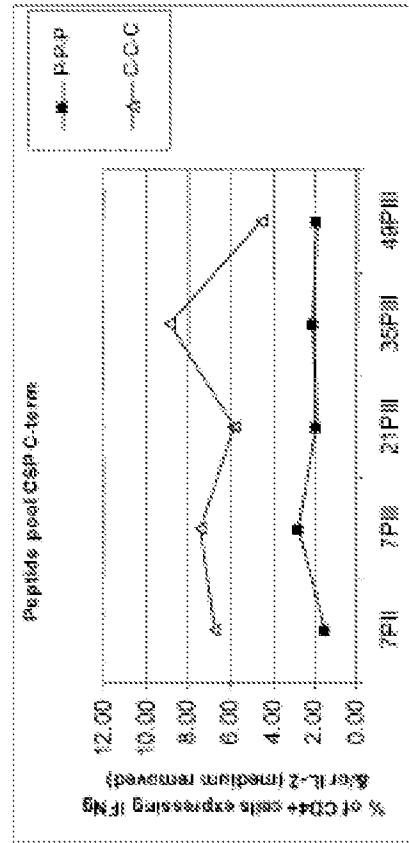


Figure 21



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Figure 22

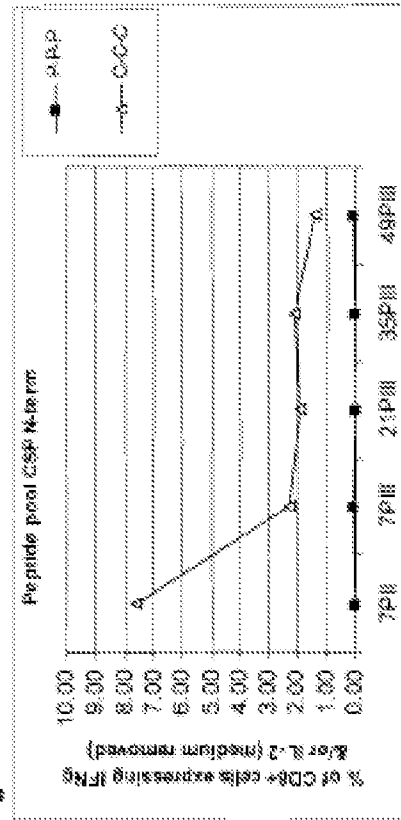
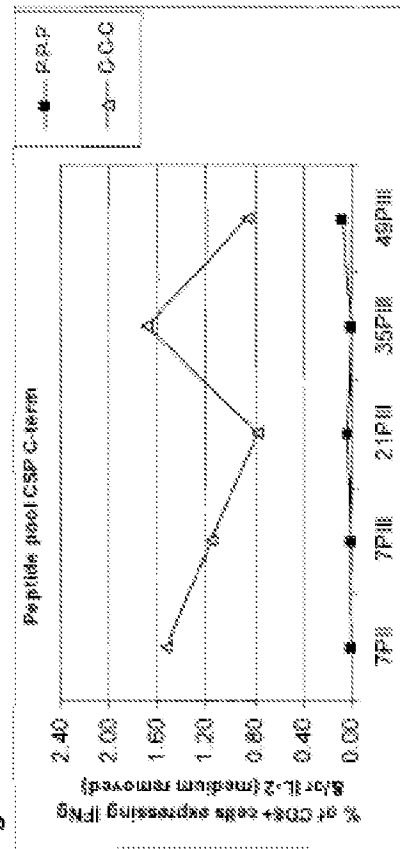
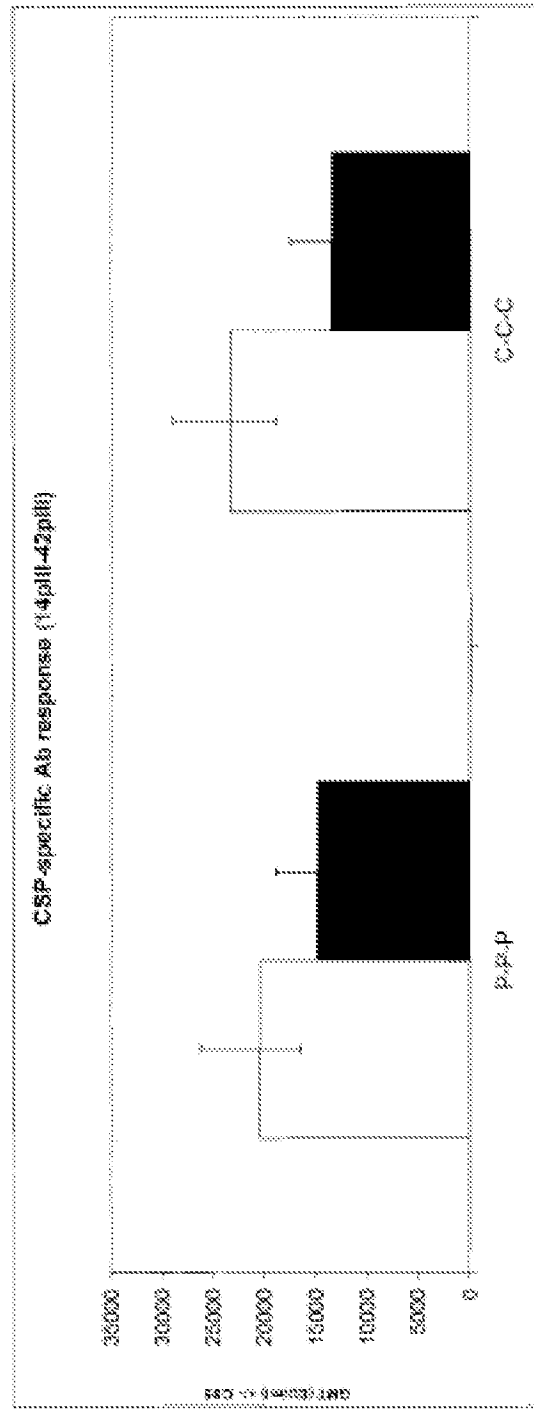


Figure 23



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Figure 24



INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2008/052448

A. CLASSIFICATION OF SUBJECT MATTER

INV. C07K14/16 C07K14/445 C12N15/861 A61K39/00

According to International Patent Classification (IPC) or to both, national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

C07K A61K C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, EMBASE, BIOSIS, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/110482 A (ISIS INNOVATION [GB]; HILL ADRIAN [GB]; MOORE ANNE C [GB]; NICOLL CLAI) 23 December 2004 (2004-12-23) the whole document	1-15, 19, 28, 34-38, 40
Y		16-18, 20-27, 29-33
Y	WO 02/22080 A (MERCK & CO INC [US]; EMINI EMILIO A [US]; YOUIL RIMA [US]; BETT ANDREW) 21 March 2002 (2002-03-21) page 22, lines 4-17 the whole document	16-18
Y	WO 2006/120034 A (GLAXO GROUP LTD [GB]; ERTL PETER FRANZ [GB]; TITE JOHN PHILIP [GB]; VA) 16 November 2006 (2006-11-16) the whole document	16-18, 20, 22
	-/-	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another claim or other special reason (as specified)
- *C* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *S* document member of the same patent family

Date of the actual completion of the international search

29 May 2008

Date of mailing of the international search report

16/06/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5010 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx. 31 661 epo nl,
Fax (+31-70) 340-3216

Authorized officer

Irlon, Andrea

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/052448

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2006/013106 A (GLAXOSMITHKLINE BIOLOG SA [BE]; ABRECHT HELGE [BE]; DELCHAMBRE MARTINE) 9 February 2006 (2006-02-09) the whole document	20, 21, 29-33
Y	WO 2007/003384 A (GLAXOSMITHKLINE BIOLOG SA [BE]; COHEN JOSEPH D [BE]) 11 January 2007 (2007-01-11) the whole document	23-27, 29-33
Y	GANNE V ET AL: "Enhancement of the efficacy of a replication-defective adenovirus-vectored vaccine by the addition of oil adjuvants" VACCINE, BUTTERWORTH SCIENTIFIC, GUILDFORD, GB, vol. 12, no. 13, 1 January 1994 (1994-01-01), pages 1190-1196, XP002393618 ISSN: 0264-410X the whole document table 1	32

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2008/052448

Box No. II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 1-7, 9-34, 39, and 40 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, the Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2008/052448

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